AVEO's Tivozanib in Combination with FOLFOX6 Demonstrates Anti-tumor Activity and Safety in Advanced GI Cancers; Results Presented at EORTC-NCI-AACR Symposium

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Preclinical Data Presented Demonstrates that Combining Tivozanib with Chemotherapy Regimens Inhibits Breast Tumor Growth and Prevents Development of Resistance

CAMBRIDGE, Mass. & BERLIN, Nov 18, 2010 (BUSINESS WIRE) -- AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today announced results from a Phase 1b clinical trial evaluating the company's lead product candidate, tivozanib, a highly potent and selective inhibitor of VEGF receptors 1, 2, and 3, in combination with FOLFOX6, a standard chemotherapy regimen, in patients with advanced gastrointestinal (GI) cancers. Results show partial responses in more than a third (35 percent) of patients evaluated (n=17) and disease control in 82 percent of patients; and, the combination was considered safe in the Phase 1b clinical trial at the full recommended tivozanib dose (1.5 mg/day) and standard FOLFOX6 dose. These data were presented today during the 22nd Annual Symposium of the European Organization for Research and Treatment of Cancer-National Cancer Institute-American Association for Cancer Research (EORTC-NCI-AACR) in Berlin, Germany.

"Safe combinations of anti-cancer therapies may be critical to ensuring optimal treatment for patients with advanced gastrointestinal cancers, as toxicities associated with many currently available targeted therapies can limit opportunities for a combination approach," commented Ferry Eskens, M.D., Ph.D., department of medical oncology, Erasmus University Medical Center, Rotterdam, Netherlands, and lead investigator of the study. "The results observed in the tivozanib Phase 1b combination study with FOLFOX6 indicate encouraging anti-tumor activity and favorable tolerability in patients living with colorectal, pancreatic and esophageal cancers."

The Phase 1b open-label, dose-escalation study assessed once-daily, oral tivozanib (sequential cohorts of 0.5, 1.0, and 1.5 mg/day for three weeks on, one week off) and FOLFOX6 (IV every 14 days) in 22 patients with advanced gastrointestinal cancers who had been treated with no more than two prior chemotherapy regimens. FOLFOX6 is a standard chemotherapy regimen widely used to treat colorectal, pancreatic and esophageal cancers. For assessment of tolerability, treatment was continued for a minimum of four weeks, or until disease progression or unacceptable toxicity; for assessment of anti-tumor activity, treatment was continued for a minimum of eight weeks (two consecutive dosing cycles). Following are key results from the study:

- Partial responses were observed in six out of 17 patients evaluated, including one patient who experienced tumor shrinkage exceeding 50 percent, as evaluated by standard Response Evaluation Criteria in Solid Tumors (RECIST)
- Stable disease was observed in an additional eight out of the 17 patients evaluated using standard RECIST
- Treatment-related side effects seen in greater-than or equal to 20% of patients included nausea, fatigue, vomiting, constipation, decreased appetite, peripheral sensory neuropathy, headache, stomatitis, diarrhea and dysphonia
- Drug-related adverse events were not observed in association with the combination that were more frequent or severe than those observed in previous studies with FOLFOX6 or tivozanib alone

"We believe the results from this Phase 1b trial evaluating tivozanib in combination with FOLFOX6 in patients with GI cancers further underscore the potential role tivozanib may play as a valuable addition to widely used chemotherapy regimens," said William Slichenmyer, M.D., Sc.M., chief medical officer at AVEO. "To date, tivozanib has demonstrated full-dose combinability in Phase 1 clinical trials with other targeted and chemotherapy treatment options, including temsirolimus. These data, in addition to positive tivozanib Phase 2 monotherapy data in patients with advanced kidney cancer, indicate significant potential for tivozanib across multiple tumor types."

Preclinical Combination Data in Breast Cancer Model

Results from a preclinical study evaluating the activity of tivozanib and capecitabine, 5-fluorouracil (5-FU) and docetaxel, as single agents and in combination, in genetically engineered HER2 driven as well as traditional breast tumor models were also presented at the meeting. These data demonstrate that addition of capecitabine to tivozanib in a tivozanib resistant HER2 driven breast tumor model led to complete tumor growth inhibition (TGI), effectively reversing tivozanib resistance in the model. In the traditional breast tumor model, tivozanib monotherapy exhibited encouraging TGI, with modest improvements in TGI when combined with 5-

FU or docetaxel. Following discontinuation of tivozanib alone or in combination with 5-FU, tumor regrowth was observed, whereas mice treated with tivozanib plus docetaxel were tumor-free by day 34 of the study, with no tumor recurrence at day 63.

Dr. Slichenmyer added, "We believe these preclinical data suggest tivozanib may be uniquely suited to combination therapy to potentially amplify treatment efficacy and combat drug resistance. We look forward to further understanding the potential utility of tivozanib as a treatment for breast cancer through ongoing and planned clinical trials."

About Tivozanib

Tivozanib, an investigational new drug, is a highly potent and selective inhibitor of VEGF receptors 1, 2 and 3, exhibiting picomolar inhibitory activity against all three receptors. Due to its potency and specificity, AVEO believes tivozanib may enable optimal inhibition of the VEGF pathway, while minimizing side effects associated with off-target activity. Such a profile may enable tivozanib to be more readily combined with standard chemotherapy as well as other targeted therapies, potentially increasing the breadth of its clinical utility. The EMA has granted AVEO orphan medicinal product designation for tivozanib for the treatment of advanced renal cell cancer (RCC).

AVEO recently completed patient enrollment ahead of schedule in TIVO-1, a global, randomized (1:1), controlled Phase 3 clinical trial evaluating tivozanib compared to sorafenib (Nexavar$^{(R)}$) in patients with RCC. The company has initiated a series of clinical trials evaluating tivozanib in combination with other agents in multiple solid tumor settings, including an ongoing Phase 1b trial in combination with temsirolimus (Torisel$^{(R)}$), an approved mTOR inhibitor, in patients with metastatic renal cell carcinoma; a Phase 1b trial in combination with the FOLFOX6 chemotherapy regimen in patients with advanced colorectal cancer and other gastrointestinal cancers; a Phase 1b trial in combination with paclitaxel (Taxol$^{(R)}$) in patients with metastatic breast cancer; and a Phase 1b trial in combination with oral capecitabine (Xeloda$^{(R)}$) in patients with advanced breast and colorectal cancers. A Phase 1b trial evaluating tivozanib as monotherapy in patients with non-small cell lung cancer is also being conducted.

AVEO is also utilizing its Human Response Platform(TM) in its efforts to help identify rational drug combinations and patient populations most likely to be responsive to these combination therapies.

About AVEO

AVEO Pharmaceuticals (NASDAQ: AVEO) integrates a proprietary cancer biology platform with drug development and commercial expertise in its efforts to discover and develop targeted cancer therapeutics. The company's lead product, tivozanib, is an oral, triple VEGF receptor inhibitor with a highly differentiated profile. Tivozanib is currently being investigated in a global, randomized Phase 3 clinical trial called TIVO-1 comparing tivozanib to sorafenib in advanced kidney cancer, as well as additional clinical studies in other solid tumor types. AVEO's second most advanced product candidate, AV-299, is a potent, functional anti-HGF antibody that is currently in Phase 2 development. AVEO's proprietary, integrated cancer biology platform offers the company a unique advantage in oncology drug development and has provided a discovery engine for high-value targets. This approach has resulted in a promising pipeline of monoclonal antibodies against novel targets including HGF, ErbB3, RON, Notch and FGFR. For more information, please visit the company's website at www.aveopharma.com.

Forward-Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about tivozanib's anti-tumor activity and tolerability profile; the potential role tivozanib may play as an addition to chemotherapy regimens and its potential across multiple tumor types; the potential for tivozanib to have broad applicability and combinability with other therapeutic agents; tivozanib possibly enabling optimal inhibition of the VEGF pathway, while minimizing side effects; our cancer biology platform offering a unique advantage in oncology drug development; and other statements containing the words "believes," "anticipates," "plans," "expects," "will" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: our ability to successfully research, develop and obtain and maintain regulatory approvals for tivozanib and our other product candidates; the possibility that favorable data from the preclinical and Phase 1b clinical trials described in this press release and our other preclinical and clinical trials of tivozanib may not be predictive of the results in future preclinical and clinical trials; delays in data availability, or negative results from our clinical trials; our inability to obtain and maintain adequate protection for intellectual property

rights relating to our product candidates and technologies; unplanned operating expenses; our inability to raise substantial additional funds to achieve our goals, including with respect to the further development of tivozanib; competition; general economic and industry conditions; and other factors discussed in the "Risk Factors" section of our most recent Form 10-Q filed with the Securities and Exchange Commission, and in other filings that we periodically make with the SEC. In addition, the forward-looking statements included in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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